

DEC 21 2005

VAPORMAX™ II Side Firing Fiber

K053457

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information: Trimedyne, Inc.
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949-951-3800

Contact Person: Glenn Yeik
President and COO

Summary Date: 22 November 2005

II. Device Name

Proprietary: VAPORMAX™ II
Common: Laser Fiber
Classification: Accessory to Laser-Powered Instrument

III. Predicate Device

The predicate devices for the VAPORMAX II Side Firing Fiber are:

- VAPORMAX™ Side Firing Fiber cleared under K050412; and
- UROLASE® Right Angle Laser Fiber cleared under K944204, K954597, and K970422.

IV. Device Description

The VAPORMAX II is a single use, disposable, side firing, fiber optic energy delivery device for use with cleared Holmium:YAG lasers.

V. Intended Use

The VAPORMAX II is intended for incision, excision, ablation, vaporization, and coagulation of soft tissue and may be used with any cleared Holmium laser that has a compatible connector.

VI. Technological Characteristics

Like its UROLASE predicate, the VAPORMAX II emits laser energy at an approximately 90-degree angle by way of direct reflection. The VAPORMAX II shares most of its design characteristics and all materials with its VAPORMAX predicate and can therefore be used with up to 100 watts of laser power.

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VII. Nonclinical Data

No nonclinical data were submitted in this Premarket Notification.

VIII. Clinical Data

No clinical tests were submitted in this Premarket Notification.

IX. Conclusions

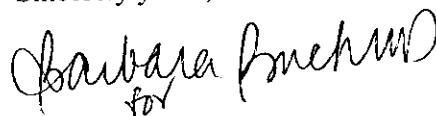
The VAPORMAX II performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

Public Health Service

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Barbara Melkerson" with a stylized flourish at the end. Below the signature, the word "for" is written in small, handwritten letters.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053457

Device Name: VAPORMAX™ II

Indications for Use:

The VAPORMAX II is intended for surgical use including: incision, excision, vaporization, ablation, and coagulation of soft tissue.

The VAPORMAX II is indicated for use with any cleared Holmium:YAG 2.1 micrometer laser with a compatible connector for that laser's cleared indications for use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Paula R. Buckner, G. M.D.
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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